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SC to start final hearing on Novartis' case on Sec 3(d) of Patents Act on August 22

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The final hearing on the controversial case on Sec 3(d) of Indian Patents Act will begin in the Supreme Court on August 22. In this high-voltage case, Novartis is challenging Section 3(d) of India's Patents Act which prohibits 'evergreening' - the practice of multinational pharmaceutical companies to extend their patent terms by making small and trivial changes to existing molecules and thereby preventing manufacture of generic drugs.

In this Special Leave Petition (SLP), the Swiss pharma major is challenging the decision of the Intellectual Property Appellate Board (IPAB) which rejected its appeal for a patent on the beta-crystalline form of Imatinib Mesylate, an anti-cancer drug.

The case was pending in the court for quite some time. It was listed before the Supreme Court on 17 October 2011, but was adjourned to January 17, 2012 for final hearing. However, due to other cases being scheduled around the same time, the hearing of Novartis' SLP and other related petitions was preponed to November 29, 2011. The case was listed for hearing on November 29 before a Division Bench of the Supreme Court, comprising Justice Aftab Alam and Justice Ranjana P Desai, which again adjourned the matter to February 28, 2012.

But once again, the case was rescheduled for March 28 as the Mumbai terror attack trial in the Supreme Court has been running later than anticipated, and Justice Aftab Alam, who has been hearing the Mumbai attack case, is also part of the two-judge bench that will hear the Novartis case. Now, the final arguments will begin on August 22, 2012.

The Supreme Court case, between Novartis and the government of India, is the final act in a legal battle that stretches back to six years over India's future capacity to produce low-cost generic medicines for its people, and for patients in other developing countries.

Novartis patented the molecule Imatinib in 1993. After the signing of the WTO TRIPS agreement by India in 1995, Novartis filed another patent application on the Mesylate salt form of Imatinib in 1998 at the Indian patent office. In 2005 India amended its patent law to comply with the WTO TRIPS agreement but also included Section 3(d), an important health safeguard that does not allow companies to get patents on new forms of old medicines.

Novartis' application was rejected by the Indian patent office on several grounds including that the application claimed a new form of an already existing medicine. The company then sued the Indian government, cancer patients and several generic companies in order to get its patent monopoly on Imatinib Mesylate by getting Section 3(d) knocked out of the patent law.

Simultaneously, Novartis pursued a separate appeal of the denial of its patent application on Glivec arguing that it met the standards of India law. When its administrative appeal failed, Novartis appealed again, this time to the Indian Supreme Court to try and change the interpretation of Section 3(d). In essence, Novartis wants section 3(d), which requires stringent

evidence of proof of significantly enhanced therapeutic efficacy if a modification of an existing pharmaceutical entity is to receive new patent protection, to be reinterpreted to allow routine "ever-greening" of minor modifications to existing medicines resulting in additional 20-year patent monopoly.